

the threads "so as not form a sharp angle" (English translation: page 6, lines 9; page 7, lines 5-10). Kuriwaka makes the additional improvement of incorporating a screw shaft 20 or 33 or 42 so as to minimize trauma to the natural tendon or ligament (English translation: page 4, lines 11 and 15-19; page 5, lines 7-13 and 21-24; page 11, lines 13-19) as the outer tubular body 10 is screwed into the borehole 2 (English translation: page 8, lines 22-27; page 9, lines 8-11).

Claim 18, the pending independent claim, recites a method for the attachment of a graft of a natural tendon or ligament to a bone of a patient, including: a) forming a hole in the bone; b) disposing at least a portion of the graft in the hole; and c) inserting a fixation screw device into the hole so that the fixation screw device engages the natural tendon or ligament of the graft and presses the natural tendon or ligament of the graft directly and firmly against a sidewall of the hole in the bone.

We first address how the language of claim 18, lines 5-7, distinguishes the method of Kuriwaka. Lines 5-7 of claim 18 recite "inserting a fixation screw device into the hole so that the fixation screw device engages the natural tendon or ligament of the graft and presses the natural tendon or ligament of the graft directly and firmly against a sidewall of the hole in the bone." It is the inserting of the fixation screw device into the hole that results in the fixation screw device engaging the natural tendon or ligament of the graft and pressing the graft directly and firmly against a sidewall of the hole in the bone, not the insertion of a second member, as described in Kuriwaka.

We now address the Examiner's contention that the claimed method would be an obvious step backward. The Examiner states "Kuriwaka is aware of the prior art method of using a *single* screw (Figure 4)." The Examiner is respectfully referred to page 5, lines 7-13 of the translation, in which Kuriwaka states that the method illustrated in Figure 4 cannot be used:

However, as Fig. 4 shows, when the tapered screw shaft 54 is screwed into the borehole 52 drilled into the bone 51, the ligament replacement 53 is twisted when it is strongly clasped by the screw threads. For this reason, ligaments taken from other parts of the body or artificial ligaments cannot be used because they are cut when they are clasped directly. Accordingly, a ligament cut from other parts of the body is used with a small fragment of bone attached to its end and it is the bone fragment which is clasped between the screw shaft 54 and the borehole 52.

Clearly, the prior art method described by Kuriwaka is one in which bone fragments are clasped between the screw shaft and the borehole, not a method in which a natural tendon or ligament of a graft is pressed directly and firmly against a sidewall of the hole in the bone, as claimed. Furthermore, the language "so as not form a sharp angle" and the passages at English translation: page 6, lines 9; page 7, lines 5-10, cited by the Examiner, refer to Kuriwaka's outer tubular body, not to the screw of Fig. 4.

Lastly, the Examiner contends that Kuriwaka makes the additional improvement of incorporating a screw shaft 20 or 33 or 42 so as to minimize trauma to the natural tendon or ligament as the outer tubular body 10 is screwed into the borehole 2. Applicants respectfully submit that, in fact, among other advantages, the invention significantly simplifies (and shortens) the surgical procedure and reduces patient trauma (and healing time) by utilizing a single fixation screw device that secures the natural tendon or ligament in the hole in the bone. Replacing Kuriwaka's two devices with a single device is not a step back. Rather, it is a significant and patentable improvement over Kuriwaka.

Therefore, applicants submit that claim 18 and its dependent claims are patentable over Kuriwaka.

The Examiner has rejected claims 24, 28, 30, and 31 under 35 U.S.C. §103(a) as obvious over Kuriwaka in view of PCT Application No. 92/03980 to Roger et al.

Roger does not overcome the deficiencies in Kuriwaka discussed above. In particular, while Roger discloses a screw for anchoring a graft in a bone hole, the graft includes bony ends which are engaged by the screw. Thus, Roger's screw does not directly engage a natural tendon or ligament of the graft and press the natural tendon or ligament directly and firmly against a sidewall of the bone hole, as recited in claim 18.

Therefore claims 24, 28, 30, and 31 are patentable over Kuriwaka in view of Roger.

Claims 22 – 31 (all of which depend from claim 18) have been rejected over Hublin, alone or in combination with Roger. Although features recited in these claims are not discussed in the previously-submitted declarations, applicants note that the declarations identify the fixation screw devices that were conceived, made, and tested prior to October 28, 1994 as the "RCI screw." The RCI screw, which is also described in applicant's prior PCT application (No. PCT/AU91/00405, of record in this application as WO92/03980) is cannulated (as recited in

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claims 22, 26, 30, and 31 the present application), and has a screw thread which is devoid of an outermost cutting line (claims 23, 27, 30, and 31), has a hemispherical head at the trailing end thereof (claims 24, 28, 30, and 31), and has a screw thread which is substantially nontapered (claims 25 and 29-31). Applicants note that the present application refers to the "RCI screw" at page 13, line 20, and to the U.S. application counterpart (now, U.S. Patent No. 5,383,878) of the above-mentioned PCT application. Thus, applicants respectfully submit that the declarations are sufficient to show that applicants completed the invention recited in claims 22-31 in the United States prior to October 28, 1994, the Hublin publication date. Accordingly, applicants respectfully submit that Hublin is unavailable as a reference against the claims.

Applicants ask that all claims be allowed. A petition for an extension of time, a notice of appeal, and the required fees are enclose. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: \_\_\_\_\_

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**Version with markings to show changes made**

**In the specification:**

The title beginning at page 1, line 1, has been amended as follows:

--Method for [Anterior Cruciate Ligament] Soft Tissue Reconstruction--